

United States Senate

WASHINGTON, DC 20510

March 4, 2019

Francesca T. Grifo, Ph.D.
Scientific Integrity Official
U.S. Environmental Protection Agency (EPA)
1301 Constitution Ave. NW
Washington, DC 20460

Dear Dr. Grifo:

We write to request that you determine whether actions by EPA political appointees that appear to have prevented the review and publication of the Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS) program's formaldehyde health assessment constitute a violation of EPA's scientific integrity policy. This policy¹, among other measures, "prohibits all EPA employees, including scientists, managers, and other Agency leadership, from suppressing, altering, or otherwise impeding the timely release of scientific information."

Several Members of Congress have repeatedly² raised concerns with the long-delayed release of the formaldehyde health assessment, which has taken more than a decade and more than \$10 million of taxpayer funds to undertake. The assessment, which has been ready to be peer reviewed for almost a year and a half and might have been ready for publication had EPA followed its typical review process and timelines, reportedly concludes that formaldehyde can cause nasopharyngeal cancer and leukemia, among other risks to human health.

While some of the efforts to delay the publication of this report by EPA political appointees have been publicly disclosed³, a March 4, 2019 Government Accountability Office (GAO) report⁴ further describes some of the circumstances surrounding EPA's decision not to finalize the formaldehyde health assessment, as well as other IRIS program delays, resource constraints and diversion of IRIS personnel to support other chemical safety efforts in the Agency. We have also obtained documents that indicate that Mr. Dunlap, who is recused from working on the formaldehyde health assessment, may have directed or participated in EPA's decision to reduce the number of chemicals that will be assessed under IRIS and cease work on the formaldehyde health assessment.

¹ https://www.epa.gov/sites/production/files/2018-11/documents/sci_2018_external_factsheet.pdf

² <https://www.markey.senate.gov/news/press-releases/senators-markey-whitehouse-and-carper-demands-epas-fruit-stop-hiding-findings-of-key-study-on-health-impacts-of-toxic-formaldehyde>

³ <https://www.politico.com/story/2018/07/06/epa-formaldehyde-warnings-blocked-696628>

⁴ GAO 19-270, "Chemical Assessments: Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," <https://www.gao.gov/products/GAO-19-270>

Efforts to delay the publication of EPA's formaldehyde health assessment date back at least since 2004. At that time, Senator Inhofe asked that⁵ EPA not begin its planned update to its 1989 formaldehyde health assessment until the National Cancer Institute (NCI) completed an update of one of its own formaldehyde studies. This NCI study was not completed until 2009,⁶ and it provided more evidence of a link between exposure to formaldehyde and several types of cancer. In 2009, then-Senator Vitter refused⁷ to allow the confirmation of an EPA nominee until EPA agreed^{8 9} to send its draft formaldehyde health assessment to the National Academy of Sciences (NAS) for review. The NAS review¹⁰ took two more years to complete, and while it criticized some of EPA's methodologies, it did not refute¹¹ the linkage identified by EPA between exposure to formaldehyde and cancer. Efforts to refer other EPA IRIS health assessments and methodologies and delay their publication continued to be made through legislative provisions inserted into Congressional Appropriations bills¹² and oversight letters by then-Senator Vitter¹³, Senator Inhofe and others.

In 2018, the NAS completed its most recent review¹⁴ of the IRIS program, finding that "EPA has made 'substantial progress'" in implementing recommendations outlined in past reports," saying in its press release that "the changes in the IRIS program over such a short period of time are impressive." The draft of the formaldehyde assessment that has been stalled from being released for peer review and publication has incorporated applicable recommendations made by the NAS as well as any new scientific information that has been published during the lengthy delay.

After Andrew Wheeler was named Acting Administrator, several Members of the Environment and Public Works Committee asked him questions for the record at an August 1, 2018 hearing about the formaldehyde health assessment. His responses to these questions say that EPA "is currently developing a new approach of soliciting program input on current and future IRIS assessments, to ensure IRIS assessment activities are focused on the highest priority needs. The formaldehyde assessment will be included in this activity, which will inform our next steps."

Mr. Wheeler was also asked several questions on this topic for the record of his January 16, 2019 confirmation hearing, and stated that "[b]ecause IRIS assessments are major investments in both time and resources, in an August 10, 2018 Memorandum to Agency program offices I requested an update of top priorities for IRIS assessments. Formaldehyde was not identified as a top priority."

⁵ https://s3.amazonaws.com/propublica/assets/docs/leavitt_inhofe_letter_041105.pdf

⁶ <https://www.propublica.org/article/study-reinforces-links-between-formaldehyde-and-cancer-518>

⁷ <https://www.scientificamerican.com/article/vitter-formaldehyde-epa/>

⁸ https://www.nola.com/politics/2009/12/sen_david_vitter_and_epa_reach.html

⁹ <http://www.documentcloud.org/documents/1598-documents-related-to-sen-vitter-and-formaldehyde-regulation.html#document/p9>

¹⁰ <https://www.nap.edu/read/13142/chapter/1>

¹¹ <https://www.nrdc.org/experts/jennifer-sass/national-academy-sciences-formaldehyde-still-causes-cancer-humans>

¹² <https://www.nrdc.org/experts/daniel-rosenberg/cancer-causing-chemicals-have-more-friends-congress-you-do-part-one>

¹³ <https://www.americanchemistry.com/Policy/Regulatory-Reform/Senators-Vitter-Inhofe-Crapo-Letter-Requesting-Greater-Clarity-on-Process-to-Assess-Chemicals.pdf>

¹⁴ <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=25086>

Mr. Wheeler's response failed to fully describe the reason why formaldehyde was not identified as a top priority for the program offices. Specifically:

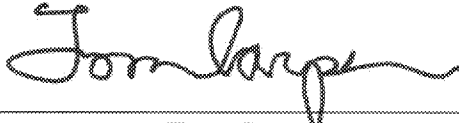
- A May, 2018 Draft EPA IRIS Program Outlook (attached) prepared by the program's Director indicated that the formaldehyde health assessment would be released for public comment (following inter- and intra-agency peer review) in the fourth quarter of FY 2019.
- An August, 2018 memo (attached) sent by Jennifer Orme-Zavaleta, Ph.D., the Principal Deputy Assistant Administrator in EPA's Office of Research and Development, requested that EPA Program offices describe their IRIS priorities, noting that the formaldehyde health assessment would be ready for review by other agencies by the fourth quarter of 2018. Her memo also noted that in the past, EPA's Office of Chemical Safety and Pollution Prevention, Office of Air and Radiation, Office of Water, Office of Children's Health Protection and Regions 2 and 5 all had expressed an interest in the completion of the formaldehyde health assessment.
- EPA's Office of Children's Health Protection, Office of Land and Emergency Management, Office of Water, and Region 4 all responded (Attached) to Dr. Orme-Zavaleta's memo saying that they had a need for the formaldehyde health assessment. The Office of Chemical Safety and Pollution Prevention did not indicate such a need in its response and noted different priorities, while the Office of Air and Radiation did not indicate a need for any IRIS assessments to be completed at all.
- In October, 2018, EPA political officials made a second request for EPA program offices to indicate what their IRIS priorities were, and this time the program offices were told to select fewer chemicals for assessment. According to GAO's records of interviews with IRIS program staff, "they said that the Administrator has his own political agenda, and that will determine their priorities. The Administrator said that he needed to make a decision on formaldehyde one way or another – it couldn't just stay in limbo forever." Furthermore, "IRIS officials said that the "priority" survey in late October was actually a request made in person at a senior political meeting, and came from David Dunlap... They think Mr. Dunlap asked Assistant Administrators to give ORD lists of their top three priority assessments."
- EPA program offices then re-submitted new lists (Attached) of priority chemicals for assessments, and this time, formaldehyde was not included on any office's priority list.
- On December 4, 2018, Jennifer Orme-Zavaleta, Ph.D., the Principal Deputy Assistant Administrator in EPA's Office of Research and Development, sent a new memo (Attached) entitled "Updated Priorities for IRIS Assessments" that did not include formaldehyde.

EPA's continued delay in publishing a report that describes the cancer risk associated with exposure to formaldehyde will do nothing to eliminate or reduce that risk. Moreover, delaying this scientific report, which has taken years to complete, may violate EPA's scientific integrity policy. We urge you to determine quickly whether that is in fact the case.

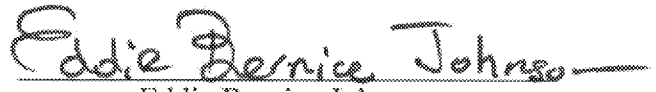
Thank you very much for your attention to this important matter. If you have any questions or concerns, please ask your staff to contact Michal Freedhoff of the Senate Environment and Public Works Committee staff at 202-224-8832, Priyanka Hooghan of the House Science, Space,

and Technology Committee staff at (202) 225-6375, Avenel Joseph of Senator Markey's office at (202) 224-2742, or Dan Dudis of Senator Whitehouse's office at (202) 224-2921.

Sincerely,



Tom Carper
Ranking Member
Environment and Public Works
Committee
U.S. Senate



Eddie Bernice Johnson
Chairwoman
Science, Space, and Technology
Committee
U.S. House of Representatives



Edward J. Markey
United States Senator



Sheldon Whitehouse
United States Senator